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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,200	04/03/2001	Douglas A. Russell	16712.0031	5401

23767 7590 08/06/2002

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/06/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/824,200

Applicant(s)

RUSSELL ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 14-19, 21 and 23-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 20, 22, 91 and 92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22, 82-87, 89, 91 and 92 and the species of Signal Sequence 3 and G-CSF in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there would be no serious search burden in examining the claims together. This is not found persuasive for several reasons. First, the separate classification of the Groups is prima facie evidence of burden which has not been rebutted by any evidence by Applicant. Second, the search and consideration are different for each Group since a different search would be performed, for example, to determine the novelty of a cytokine relative to the novelty of an expression method.

Applicant further argues that the election of species is improper because there is no burden on examining all the species. This appears to be an admission that the species are obvious variants of one another, since Applicant's argument makes no sense if the species are, in fact, patentably distinct. If Applicant did intend such an admission, Applicant is requested to clearly state on the record that the species are not patentably distinct and are obvious variants of one another.

Consequently claims 11, 12, 14-19, 21, 23-81, 82-90 are drawn to nonelected inventions, either to non-elected groups or to nonelected species (e.g., claims 82-87 are drawn to growth hormone and not G-CSF), and will not be examined.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities:

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. (For example, see page 17, line 12).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-7, 9, 10, 13, 20, 91 and 92 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent 6,020,169).

Lee teaches a method for producing a cytokine, such as IL-4, which is free from amino acid modifications or novel glycosylation (see figure 13 which shows that IL-4 has same molecular weight as recombinant human IL-4) in a plant host system wherein said plant host system has been transformed with a chimeric nucleic acid sequence encoding said cytokine (see column 6, lines 6-21 and column 20, lines 15-67) comprising the steps:

(a) cultivating said transformed plant host system under the appropriate conditions to result in the expression of said cytokine in said plant host system (see column 20, lines 15-67)

(b) wherein said cytokine accumulates to a level greater than 1% of the total soluble protein in a sample of said plant host system (see figure 11, where clone 81 produced over 1000 ng of IL-4 per g Calli, which inherently represents more than 1% of the total soluble protein). Lee also expressly teaches that expression of over 1% of total protein is achievable (see column 1, line 45).

Lee purifies the cytokine using SDS-PAGE and TCA precipitation (see column 21, lines 7-16).

Lee teaches a chimeric nucleic acid molecule which comprises the cloned plant cytokine gene (see column 9, lines 58-60) under the control of a plant promoter sequence (see column 9, line 60 to column 10, line 2) as well as signal sequences including signal sequences to the endoplasmic reticulum (see column 5, line 51 to column 6, line 5).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (U.S. Patent 6,020,169) as applied to claims 1-7, 9, 10, 13, 20, 91 and 92 above, in view of Boone et al (U.S. Patent 5,849,883).

Lee teaches a method for producing a cytokine, such as IL-4, which is free from amino acid modifications or novel glycosylation (see figure 13 which shows that IL-4 has same molecular weight as recombinant human IL-4) in a plant host system wherein said plant host system has been transformed with a chimeric nucleic acid sequence encoding said cytokine (see column 6, lines 6-21 and column 20, lines 15-67) comprising the steps:

(a) cultivating said transformed plant host system under the appropriate conditions to result in the expression of said cytokine in said plant host system (see column 20, lines 15-67)

(b) wherein said cytokine accumulates to a level greater than 1% of the total soluble protein in a sample of said plant host system (see figure 11, where clone 81 produced over 1000 ng of IL-4 per g Calli, which inherently represents more than 1% of

the total soluble protein). Lee also expressly teaches that expression of over 1% of total protein is achievable (see column 1, line 45).

Lee purifies the cytokine using SDS-PAGE and TCA precipitation (see column 21, lines 7-16).

Lee teaches a chimeric nucleic acid molecule which comprises the cloned plant cytokine gene (see column 9, lines 58-60) under the control of a plant promoter sequence (see column 9, line 60 to column 10, line 2) as well as signal sequences including signal sequences to the endoplasmic reticulum (see column 5, line 51 to column 6, line 5).

While Lee teaches expression of GM-CSF (see column 22, example 4), Lee does not expressly teach expression of G-CSF in plants.

Boone suggests expression of G-CSF in plants (see column 10, line 9).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to express G-CSF in plants using the method of Lee since Boone expressly teaches that the G-CSF polypeptides can be the product of "prokaryotic or eukaryotic host expression (e.g. by bacterial, yeast, higher plant, insect and mammalian cells in culture)(see column 10, lines 6-9)". An ordinary practitioner, taught by Lee a method which teaches "high-level gene expression (abstract)" in plants would have been motivated to apply this high level gene expression method to express the G-CSF of Boone since Boone expressly suggests plant cell expression of the protein. Further an ordinary practitioner would have been motivated in order to get more protein, since Lee teaches high level expression.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (U.S. Patent 6,020,169) in view of Schouten et al (FEBS Lett. (1997) 415:235-241).

Lee teaches the limitations of claims 1-7, 9, 10, 13, 20, 91 and 92 as discussed above. Lee teaches signal sequences for ER expression (see columns 5 and 6) but Lee does not teach the use of KDEL sequence at the 3' end of the sequence.

Schouten teaches the use of a KDEL sequence at the 3' end of proteins for ER expression (see abstract, page 235, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to utilize the KDEL sequence of Schouten in the cytokine expression method of Lee since Schouten states "It was unexpectedly shown that addition at the C-terminus of the ER retention signal KDEL resulted in significantly improved expression levels (abstract)". An ordinary practitioner would have been motivated to use the KDEL retention signal of Schouten in the expression method of Lee in order to achieve significantly improved expression levels, since more protein is the desired result by any ordinary practitioner.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

August 5, 2002